tenor,

"Para examinar la acción de violación ejercitada por vía reconvencional (y de modo simétrico la acción de jactancia pretendida por la demandante que fue estimada por la sentencia de 1ª Instancia), no es ocioso advertir que la teoría de las reivindicaciones, determinante de la eficaz protección del derecho de los inventores (y que resulta aplicable a los modelos de utilidad por la remisión que efectúa el artículo 154), no quiebra por la simple introducción de cualquier modificación irrelevante que destruya la absoluta identidad entre el modelo controvertido con el que fue registrado por el accionante, lo que conforma la llamada teoría de los □equivalentes□ (a la que se refirió la demandante en el acto de la vista y de la que hablaba nuestra sentencia de 14 de enero de 1.999 -Rollo 131/97-), entendiendo por tales, como decía la STS (Sala 3ª) de 10 de junio de 1.968, "las variantes de forma, materia, tamaño, disposición de elementos e, incluso, toda sustitución de esos elementos por otros, cuando con ello no se altere el principio fundamental de la invención descrita, reivindicada y amparada por la patente o el modelo de utilidad", o cuando "dos medios cumplen la misma función para conseguir idéntico resultado pese a que los modos de realización sean diferentes", cumpliendo la misma función "cuando proceden de la misma idea fundamental, es decir, cuando aplican el mismo principio de la misma manera", siendo idéntico el resultado cuando "es de la misma naturaleza y de la misma calidad" (decisión de 15 de junio de 1.994 en el recurso T 697/92 de la Oficina Española de□ Patentes).

SÉPTIMO.- El reconocimiento de los aparatos aportados a las actuaciones comercializados por SOLAC, S.A, denominados "Professional Epil"", "Super Epil" e "Hidratant Epil", pone de manifiesto la existencia de una serie de circunstancias comunes con los descritos por el modelo nº 8900037 que recoge el antedicho informe emitido por la OEPyM -f. 1.469-, a saber: a) se constituyen a partir de una casaca formada por dos semicarcasas; b) en el interior de la carcasa va alojada una camisa; c) las carcasas se dividen en dos partes según un plano longitudinal; d) en la superficie lateral y externa de la camisa se adosan unas resistencias; e) los depósitos contenedores de cera presentan una configuración e a la de la carcasa que los acoge; f) las resistencias, en este concreto aparato, están gobernadas por un termostato fijo para mantener una temperatura idónea de la aplicación de la cera; g) la carcasa, la camisa y las resistencias eléctricas, se acoplan de manera que se consigue un pequeño cuerpo, que unido a un depósito contenedor complementario consigue que se lleve a cabo un proceso depilador en el que la cera se mantiene caliente durante todo el proceso de depilación; h) el aplicador de ceras es portable.

Sin perjuicio de las diferencias en lo que se dio en llamar la filosofía de uso de los utensilios puestos en comparación (así se manifestó el

perito que actuó en el procedimiento 866/96 seguido ante el Juzgado nº 43 de los de Barcelona), las restantes existentes entre ambos (venir conformado por una pieza el aparato de las demandadas y por dos el de la actora, poseer mando de asido e interruptor aquél y no éste y disfrutar de conexión constante a la red el protegido por el modelo de utilidad 8900037 - que puede ser eliminada mediante la función que está llamada a desempeñar el aparato sin menoscabo de la misma- y no el comercializado por la demandante), pueden reputarse intrascendentes, toda vez que la finalidad y el modo de operar de los instrumentos examinados resultan ser los mismos. Así concluye el repetido informe de la OEPyM -f. 1.472- y a dicha conclusión llega la Sala, lo que significa la revocación de la sentencia apelada y la estimación de la demanda reconvencional interpuesta por las demandadas con las consecuencias de cesación, embargo y destrucción de todos los productos que infringen el derecho protegido y de los moldes utilizados por ELECTRODOMÉSTICOS SOLAC, S.A para la fabricación de los mismos".

4.- **La falta de toda virtualidad de una eventual alegación en contrario basada en la patente de LABORATORIOS BELMAC, S.A. nº 2192929: artículos 55 y 56 invocables al respecto**

El hecho de que **LABORATORIOS BELMAC, S.A.** sea titular de una patente de invención para la fabricación de Omeprazol –al margen de que pueda o no estar siendo utilizado- no exonera a la demandada de su responsabilidad por infracción de la patente ES 9301319.

(a) La patente nº 2192929 fue solicitada por la demandada en fecha posterior a la patente de **ETHYPHARM, S.A.** y en relación con una tecnología que le había sido facilitada por la propia actora y que venía aplicando en la maquinaria propiedad de la actora. Debemos recordar al respecto que los derechos deben ejercitarse conforme a las exigencias de la buena fe y que el ordenamiento no ampara ni el abuso del derecho ni los actos ejecutados en fraude de ley. Los artículos 6.4 y 7 del Código Civil constituyen un punto de partida de elemental observancia al respecto.

(b) La Ley de Patentes regula expresamente este tipo de casos en los que el demandado pretende amparar su actuación en un título registral posterior a aquél que fundamenta la acción por violación interpuesta en su contra. Nos referimos al artículo 55 de la Ley, según el cual:

> *"El titular de una patente no podrá invocarla para defenderse frente a las acciones dirigidas contra él por violación de otras patentes que tengan una fecha de prioridad anterior a la de la suya"*

La desaparición de estas llamadas "*patentes de cobertura*" constituye uno de los logros más aplaudidos de la ya lejana reforma del derecho de patentes en nuestro país. El efecto de esta supresión es muy claro y ha sido explícitamente recogido en la sentencia de la Sala Primera del Tribunal Supremo de 19 de octubre de 1993 (RJ 7742):

> *"Ha de tenerse en cuenta que ejercitada en los autos una acción por violación del derecho de patente registrado a favor de don José B.P. el núcleo de la cuestión es, como señala la sentencia recurrida, el de determinar si estas máquinas fabricadas por el demandado son iguales a las patentadas por el actor; por lo que, como establece el Art. 55 LP, el titular de una patente no podrá invocarla para defenderse frente a las acciones dirigidas contra él por violación de otras patentes que tengan una fecha de prioridad anterior a la suya, prioridad que, en el caso, juega a favor del actor recurrido, es decir, no se trata de realizar un examen comparativo entre las reivindicaciones de una y otra patente, cuanto de precisar si las máquinas que se dicen construidas infringiendo el derecho de patente del actor son sustancialmente idénticas a las protegidas por esa patente o, por el contrario, introducen novedades que entrañan una actividad inventiva [...]"*

(c) Aun pasando por alto estas dos consideraciones anteriores, todavía la patente no podría jugar papel alguno en la controversia en la medida en que se trataría de una patente "*dependiente*" de la propia patente de **ETHYPHARM, S.A.** Es decir, su objeto no podría nunca ser utilizado *para* la elaboración de un Omeprazol cuya formulación está protegida por una patente anterior. La *dependencia* entre patentes está regulada explícitamente en el artículo 56 de la Ley, a cuyo tenor:

> *"El hecho de que el invento objeto de una patente no pueda ser explotado sin utilizar la invención protegida por una patente anterior perteneciente a distinto titular no será obstáculo para la validez de aquélla. En este caso ni el titular de la patente anterior podrá explotar la patente posterior durante la vigencia de ésta sin consentimiento de su titular, ni el titular de la patente posterior podrá explotar ninguna de*

> *las dos patentes durante la vigencia de la patente anterior, a no ser que cuente con el consentimiento del titular de la misma o haya tenido una licencia obligatoria*".

Es decir, sin perjuicio de que la demandada pueda hacer uso de los procesos descritos en su patente para otros fines, su utilización para la producción de Omeprazol conforme a la formulación patentada por **ETHYPHARM, S.A.** requeriría el consentimiento explícito de esta última, en la medida en que el objeto de esta patente no podrá ser explotado sin utilizar al mismo tiempo la invención protegida en la patente ES 9301319.

-III-

ACCIONES QUE COMPETEN AL TITULAR DE DERECHOS DE PATENTE

1.- Régimen general

La Ley de Patentes establece en favor del titular de un derecho de Propiedad Industrial un sistema de acciones que se estructura en torno a tres pretensiones básicas: la de cesación de la conducta infractora (la suspensión de la fabricación y venta del producto infractor), la de remoción de los efectos e instrumentos de la violación (la retirada del mercado y destrucción de los ejemplares ilícitos) y la de resarcimiento por los daños y perjuicios causados (la indemnización económica).

Así, el artículo 62 de la Ley dispone que el titular de una patente y, así mismo el titular de un modelo de utilidad en virtud de las remisiones de los artículos 152 y 154,

> *"Podrá ejercitar ante los órganos de la Jurisdicción ordinaria, las acciones que correspondan, cualquiera que sea su clase y naturaleza, contra quienes lesionen su derecho y exigir las medidas necesarias para su salvaguardia".*

El contenido concreto de las acciones de cesación y remoción se establece en el artículo 63, a cuyo tenor:

"El titular cuyo derecho de patente sea lesionado podrá, en especial, solicitar:

a) La cesación de los actos que violen su derecho.

b) La indemnización de los daños y perjuicios sufridos.

c) El embargo de los objetos producidos o importados con violación de su derecho y de los medios exclusivamente destinados a tal producción o a la realización del procedimiento patentado.

d) La atribución en propiedad de los objetos o medios embargados en virtud de lo dispuesto en el apartado anterior cuando sea posible, en cuyo caso se imputará el valor de los bienes afectados al importe de la indemnización de daños y perjuicios. Si el valor mencionado excediera del importe de la indemnización concedida, el titular de la patente deberá compensar a la otra parte por el exceso.

e) La adopción de las medidas necesarias para evitar que prosiga la violación de la patente y, en particular, la transformación de los objetos o medios embargados en virtud de lo dispuesto en el apartado c), o su destrucción cuando ello fuera indispensable para impedir la violación de la patente.

f) La publicación de la sentencia condenatoria del infractor de la patente, a costa del condenado, mediante anuncios y notificaciones a las personas interesadas. Esta medida sólo será aplicable cuando la sentencia así lo aprecia expresamente".

2.- La pretensión de resarcimiento

La Ley pone especial cuidado en la regulación de la acción indemnizatoria. Para el artículo 64,

"1. Quien, sin consentimiento del titular de la patente, fabrique, importe objetos protegidos por ella o utilice el procedimiento patentado, estará obligado en todo caso a responder de los daños y perjuicios causados"

Para la determinación de los daños y perjuicios, la Ley proporciona dos criterios acumulativos y tres parámetros optativos en relación al segundo de los mismos. De conformidad con lo dispuesto en el artículo 66,

"1. La indemnización de daños y perjuicios debida al titular de la patente comprenderá no sólo el valor de la pérdida que haya sufrido, sino también el de la ganancia que haya dejado de obtener el titular a causa de la violación de su derecho.

2. La ganancia dejada de obtener se fijará, a elección del perjudicado, conforme a alguno de los criterios siguientes:

a) Por los beneficios que el titular habría obtenido previsiblemente de la explotación de la invención patentada si no hubiera existido la competencia del infractor.

b) Por los beneficios que este último haya obtenido de la explotación del invento patentado.

c) Por el precio que el infractor hubiera debido pagar al titular de la patente por la concesión de una licencia que le hubiera permitido llevar a cabo su explotación conforme a derecho.

Para su fijación se tendrán en cuenta especialmente, entre otros factores, la importancia económica del invento patentado, la duración de la patente en el momento en que se comenzó la violación y el número y clase de licencias concedidas en ese momento.

3. Cuando el Juez estime que el titular no cumple con la obligación de explotar la patente establecida en el artículo 83 de la presente Ley, la ganancia dejada de obtener se fijará de acuerdo con lo establecido en la letra c) del apartado anterior."

En cuanto al período temporal de la actividad infractora sujeta a indemnización, el artículo 71.2 de la Ley de Patentes dispone:

"2. Solo podrá reclamarse indemnización de daños y perjuicios por hechos acaecidos durante los cinco años anteriores a la fecha en la que se ejercite la correspondiente acción".

3.- <u>La prueba del daño</u>

A efectos de prueba en lo que respecta a la pretensión de resarcimiento, citamos expresamente el artículo 65 de la Ley de Patentes, según el cual,

"A fin de fijar la cuantía de los daños y perjuicios sufridos por la explotación no autorizada del invento, el titular de la patente podrá exigir la exhibición de los documentos del responsable que puedan servir para aquella finalidad."

En cuanto a la interpretación jurisprudencial del daño en propiedad industrial, nos permitimos citar la Sentencia nº 1217/2004 de la Sala Primera del Tribunal Supremo de 23 de diciembre de 2004, en cuanto que repasa la jurisprudencia

existente sobre la materia y concluye en los siguiente términos:

> *"...y de ahí, también, que convenga matizar lo declarado por esta Sala en algunas de sus sentencias, sobre la imperiosa exigencia de acreditar los daños y perjuicios en el proceso de declaración (STS 20-2-01 en recurso nº 361/96), o sobre la falta de consolidación de la doctrina de los daños "in re ipsa" en estas materias (SSTS 29-9-03 en recurso nº 3908/97 y 3-3-04 en recurso nº 889/98), mediante lo resuelto por aquellas otras que consideran los daños y perjuicios una consecuencia necesaria de la infracción (SSTS 23-2-98 en recurso nº 3359/94, 17-11-99 en recurso 790/95, 7-12-01 en recurso nº 2483/96 y 19-6-03 en recurso nº 3289/97), pues raramente podrá darse la infracción que ningún beneficio reporte al infractor, o ningún perjuicio cause al demandante interesado en que cese la ilicitud, si se tiene en cuenta el interés económico que preside estos ámbitos, generalmente vinculados a actividades empresariales, e incluso la posibilidad de daño moral admitida por esta Sala en su sentencia de 18 de febrero de 1999 al resolver un recuso de casación en materia de marcas siendo demandante una persona física".*

-IV-

IMPOSICIÓN DE COSTAS

Se interesa la imposición de las costas a la demandada de conformidad con lo dispuesto en el artículo 394 de la Ley 1/2000, según el cual,

> *"En los procesos declarativos, las costas de la Primera Instancia se impondrán a la parte que haya visto rechazadas todas sus pretensiones, salvo que el Tribunal aprecie, y así lo razone, que el caso presentaba serias dudas de hecho o de derecho".*

En caso de allanamiento, citamos expresamente el párrafo segundo del artículo 394, según el cual,

> *"Se entenderá que, en todo caso, existe mala fe, si antes de presentada la demanda se hubiese formulado al demandado requerimiento fehaciente y justificado de pago, o si se hubiera dirigido contra él demanda de conciliación".*

En su virtud,

SUPLICO AL JUZGADO que teniendo por presentado este escrito con los documentos y copias que lo acompañan y por interpuesta en nombre de la compañía **ETHYPHARM, S.A.** demanda de juicio ordinario contra la compañía **LABORATORIOS BELMAC, S.A.**, acuerde admitirla y previos los trámites legales oportunos, dicte Sentencia en su día por la que:

1° DECLARE

Que el ofrecimiento, fabricación y/o comercialización por la compañía demandada **LABORATORIOS BELMAC, S.A.** de las especialidades de Omeprazol objeto de la presente acción, constituye una violación de los derechos que se derivan de las reivindicaciones 1ª a 6ª de la Patente ES 9301319.

2° CONDENE A LA DEMANDADA

a) A estar y pasar por las anteriores declaraciones.

b) A cesar de inmediato en el ofrecimiento, fabricación, comercialización, venta y/o exportación de las especialidades de Omeprazol a que refiere la demanda.

c) A abstenerse en lo sucesivo de toda actividad de ofrecimiento, fabricación, comercialización, venta y/o exportación de las especialidades farmacéuticas de Omeprazol que se encuentren comprendidas en el ámbito de las reivindicaciones de la patente ES 9301319.

d) A retirar del mercado y destruir cualesquiera catálogos, folletos o documentos en los que se consignen las referidas especialidades farmacéuticas Omeprazol, incluida la referencia en su sitio de Internet.

e) A indemnizar a la demandante **ETHYPHARM, S.A.**, por los daños y perjuicios causados, en razón del precio que hubiera debido pagar **LABORATORIOS BELMAC, S.A.** a **ETHYPHARM, S.A.** por la fabricación y venta de especialidades farmacéuticas de Omeprazol a partir del 23 de marzo de 2002 y hasta la ejecución de sentencia.

Todo ello con expresa imposición de las costas a la demandada.

OTROSI DIGO PRIMERO. Presentación de la demanda dentro del plazo establecido en el artículo 131.2 de la Ley de Patentes.

Se hace constar que el presente escrito de demanda se interpone dentro del plazo de dos meses establecido en el artículo 131.2 de la Ley de Patentes de 20 de marzo de 1986 contados a partir desde la práctica de las Diligencias de comprobación de hechos. Obviamente el *dies a quo* para el cómputo de este plazo no es otro que el de la notificación del Auto del Juzgado de Primera Instancia nº 72 de Madrid desestimatorio de la oposición el pasado 10 de febrero de 2005. Este Auto es el que hizo posible la entrega a esta parte del testimonio judicial necesario para la preparación de la demanda.

SUPLICO AL JUZGADO que tenga por hecha la anterior manifestación a los efectos oportunos.

OTROSI DIGO SEGUNDO. Requerimiento de exhibición documental por la demandada.

Que esta parte interesa, de conformidad con lo dispuesto en el artículo 328 de la Ley de Enjuiciamiento Civil que, con el emplazamiento a **LABORATORIOS BELMAC, S.A.** para que conteste a la demanda, se requiera a la demandada a fin de que aporte con su contestación la documentación siguiente:

(a) Copia de las páginas de los Protocolos de fabricación de los lotes de Omeprazol Z 104, Z 112, Z 093 donde conste la especialidad farmacéutica o destinatario a que se refiere.

(b) Copia de las páginas 33 de 33 del Protocolo de fabricación de los lotes de Omeprazol Z 022, Z 030, Z 033, Z 029 y Z 051 donde conste el balance final de los mismos.

(c) Copia de los contratos de fabricación y venta suscritos por **LABORATORIOS BELMAC, S.A.** con posterioridad al 24 de marzo de 2002 en relación con la especialidad farmacéutica Omeprazol.

(d) Copia de las licencias o cesiones suscritas con terceros por **LABORATORIOS BELMAC, S.A.** en relación con las autorizaciones farmacéuticas obtenidas para la especialidad Omeprazol.

(e) Copia de las páginas del Protocolo de elaboración de los lotes Belmazol 20 mg. Cápsulas Omeprazol (S1) ; Davur 20 mg. (V 008); Belmazol 20 mg. (V 003) y Omeprazol Farmygel (V 034) donde pueda constatarse la formulación y el balance final.

(f) Listado completo de las especialidades farmacéuticas de Omeprazol fabricadas por **LABORATORIOS BELMAC, S.A.** para sí misma o para terceros y con destino a la exportación a partir del 23 de marzo de 2002.

(g) El volumen total, certificado por auditor, de los kilogramos de Omeprazol fabricados desde el 23 de marzo de 2002 para las referidas especialidades farmacéuticas.

SUPLICO AL JUZGADO que teniendo por formulada la petición anterior requiera a la demandada, en la propia cédula de emplazamiento, para que aporte la documentación señalada con el escrito de contestación.

OTROSÍ DIGO TERCERO. Designación judicial de perito contable.

De conformidad con lo dispuesto en el artículo 339.2 de la vigente Ley de Enjuiciamiento Civil esta parte interesa la designación judicial de un perito contable a fin de que a la vista de la facturación, libros oficiales, documentos contables y cualquier otro documento necesario, tanto de la compañía **ETHYPHARM, S.A.** como de la demandada **LABORATORIOS BELMAC, S.A.**, certifique: (i) cuál era el precio medio que **LABORATORIOS BELMAC, S.A.** pagaba a **ETHYPHARM, S.A.** en relación con la fabricación y venta de especialidades farmacéuticas de Omeprazol (ii) cuál era el precio que hubiera debido pagar **LABORATORIOS BELMAC, S.A.** a **ETHYPHARM, S.A.** en

relación con la fabricación y venta por **LABORATORIOS BELMAC, S.A.** de especialidades de Omeprazol a partir del 23 de marzo de 2002.

SUPLICO AL JUZGADO que tenga por hecha la anterior manifestación a los efectos oportunos.

OTROSI DIGO CUARTO. Reserva que se efectúa para la designación judicial de perito técnico.

De conformidad con lo dispuesto en el artículo 339.2 de la vigente Ley de Enjuiciamiento Civil esta parte interesa, para el caso de una impugnación por la demandada del dictamen pericial aportado o una discrepancia acerca de su contenido y alcance, que se proceda por el Juzgado a la designación judicial de perito, proponiéndose al respecto el Centro de Patentes de la Universidad de Barcelona. El Profesor D. Pascual Ségura, a cargo de dicho Centro, cuenta con un alto prestigio y especialización en la emisión de dictámenes en materia de patentes farmacéuticas. La articulación de la prueba y concreción de los extremos a examinar será efectuada, en función de la contestación a la demanda, en el trámite de Audiencia previa o a requerimiento del Juzgado. La dirección de este Centro es la siguiente:

Parc Científic de Barcelona
Baldiri Reixac, 4.
08028 Barcelona

SUPLICO AL JUZGADO que tenga por hecha la anterior manifestación a los efectos oportunos.

OTROSI DIGO QUINTO que al tiempo de presentación de esta demanda no disponía todavía mi representada de la traducción al español de los documentos nº 9, 35 y 36. Esta traducción será presentada tan pronto como le sea entregada a esta parte.

SUPLICO AL JUZGADO que tenga por hecha la anterior manifestación a los efectos oportunos.

OTROSI DIGO SEXTO que siendo general para pleitos el poder que se acompaña,

SUPLICO AL JUZGADO que acuerde su desglose y devolución a esta parte previa constancia del mismo en Autos.

OTROSI DIGO SÉPTIMO que de conformidad con lo dispuesto en el artículo 253 de la Ley 1/2000 esta parte manifiesta que la cuantía del presente procedimiento es indeterminada y que dicha cuantía no afecta a la clase de juicio aplicable.

SUPLICO AL JUZGADO que tenga por hecha la anterior manifestación a los efectos oportunos.

OTROSI DIGO OCTAVO que esta parte tiene encomendada la dirección letrada del presente procedimiento a los Letrados del Ilustre Colegio de Abogados de Madrid, D. Antonio Castán Pérez-Gómez (Colegiado nº 24.841) y D. Enrique Armijo Chávarri (Colegiado nº 28.816), ambos con despacho profesional en Madrid, calle de Miguel Angel nº 21 (Teléfono: 91700 94 00).

SUPLICO AL JUZGADO que tenga por hecha la anterior manifestación a los efectos oportunos.

OTROSÍ DIGO NOVENO que en aplicación del Art. 135.1 de la Ley de Enjuiciamiento Civil de 1/2000, el adjunto escrito sujeto a plazo se presenta antes de las quince horas del día hábil siguiente al de vencimiento del plazo.

SUPLICO AL JUZGADO tenga por hecha la anterior manifestación a los efectos oportunos.

Por ser de Justicia que pido en Madrid, a 11 de abril de 2005.

_____

Antonio Castán

AC/MJP/::ODMA\PCDOCS\GD\72192\1

COPY

TO THE MERCANTILE COURT OF MADRID

PLAINTIFF

PLAINTIFF: ETHYPHARM, S.A.

SOLICITOR: Ms. ALMUDENA GALÁN GONZÁLEZ

ATTORNEY: Mr. ANTONIO CASTÁN PÉREZ-GÓMEZ

DEFENDANT

LABORATORIOS BELMAC, S.A.

PROCEDURE ORDINARY SUIT

OBJECT VIOLATION OF PATENT RIGHTS

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SIXTH.- THE PERSISTENCE OF LABORATORIOS BELMAC, S.A. IN THE INFRINGEMENT AFTER THE FACT VERIFICATION PROCEEDINGS WERE CARRIED OUT IN DECEMBER 2002

A) The capsules of Omeprazole manufactured by LABORATORIOS BELMAC, S.A. after 19th December 2002

B) The inexistence of any change in the formulation: the absence of the new health registrations obtained by LABORATORIOS BELMAC, S.A. for marketing Omeprazole

C) The irrelevance of ulterior patents obtained by LABORATORIOS BELMAC, S.A. for Omeprazole

D) The additional technical verification provided for the current Omeprazole manufactured by LABORATORIOS BELMAC, S.A.

SEVENTH.- THE LOSSES AND DAMAGES DERIVED FROM VIOLATION OF ETHYPHARM, S.A.'s PATENT AND FROM THE UNLOYAL BEHAVIOUR OF LABORATORIOS BELMAC, S.A.

A) The mark-up that the sale of the Omeprazole manufactured by LABORATORIOS BELMAC, S.A. represented for ETHYPHARM

B) Quantification of the damages from the manufacture and sale of Omeprazole from 23rd March 2002 onwards

GROUNDS OF LAW

-I-

BASES OF TRIAL

1. Jurisdiction and nature of trial
2. Objective competency
3. Territorial competency
4. Legitimation
5. Postulation
6. Probatory Activity

-II-

RIGHTS DERVIED FROM THE PLAINTIFF'S OWNERSHIP OF THE PATENT ES 9301319 AND INFRINGEMENT OF SAME IN THE MANUFACTURE AND SALE OF OMEPRAZOL BY THE DEFENDANT

1.- Notion and regulation for patent

2.- Scope of the right to exclusiveness in the case of *product* patents

3.- Infringement of a patent *by equivalence*

4.- Lack of any virtue in possible allegation to the contrary based on LABORATORIO BELMAC, S.A.'s patent no. 2192929: articles 55 and 56 may be invoked for this purpose

-III-

ACTIONS TO WHICH THE HOLDER OF THE PATENT RIGHTS IS ENTITLED

1.- General regime

2.- Intention to restitution

3.- Proof of damages

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2. Formulation according to the 1st claim, characterised by the fact that a perceptible 10% of the weight of the active layer of omeprazole is carboxymethyl starch.

3. Formulation according to the 2nd claim, characterised by the fact that a perceptible 5% of the active layer of omeprazole is a tensioactive compound of the sodium laurylsulphate type.

4. Formulation according to all of the claims 1 to 3, characterised by the fact that the surface of the active layer of omeprazole has a complementary protective layer of mannitol.

5.Formulation according to all of the claims 1 to 4, characterised by the fact that the omeprazole dilution in mannitol and the aforementioned protective layer are applied using a highly viscous binding agent such as hydroxypropylmethylcellulose.

6. Formulation according to all of the claims 1 to 5, characterised by the fact that the active granules have an outer layer for gastric protection composed by a gastro-resistant coating such as hydroxypropylmethylcellulose phthalate and talc.

7.Procedure for obtaining the formulation according to all of the claims 1 to 6, characterised by the fact that a dry dilution of mannitol and omeprazole is applied to the neutral granules composed of sugar and starch using a highly viscous binding solution such as hydroxypropylmethylcellulose in solution, in a mix of at least 80% of ethanol and 20% of water at the most.

8. Procedure according to claim 7, characterised by the fact that each application of the dilution is then dried, at a temperature of between 35° C and 40°C for a duration that allows to bring down the content of active microgranules in water to 1% and the ethanol content to 2,000 ppm.

9. Procedure according to claims 7 and 8, characterised by the use of neutral microgranules measuring between 0.7 and 0.9 mm.

10. Procedure according to claims 7, 8 and 9, characterised by the use of flat-bottomed turbines to apply the active dilution and the gastro-protective coatings.

We attach as DOCUMENT NO. 2, the certification accrediting the ownership and validity of the patent ES 9301319 belonging to ETHYPHARM, S.A. and as DOCUMENT NO. 3, the official certificate issued by the Spanish Patents and Trademarks Office with the text for the said patent.

B) The patent held by ETHYPHARM, S.A. includes ten claims. Claims 1 to 6 refer to a pharmaceutical formulation or product; claims 7 to 10 refer to the procedure for preparing or obtaining this formulation. The essential characteristic of the first group of claims is that the stable formulation of Omeprazole microgranules is composed of a neutral nucleus composed of sugar and starch covered by an active layer formed by a dilution of Omeprazole in mannitol in perceptibly equal quantities.

THIRD.- THE COMMERCIAL RELATIONS MAINTAINED BETWEEN THE PARTIES REGARDING THE OMEPRAZOL MANUFACTURED ACCORDING TO PATENT NO. 9301319

A) The defendant LABORATORIOS BELMAC, S.A.

The suit is directed against the company LABORATORIOS BELMAC, S.A. This firm was set up in 1991. Its main office is located in San Sebastián de los Reyes (Madrid) and its main factory is situated in Zaragoza. As may be seen from its

website www.belmac.com, the defendant's activity is focused on products acting on the digestive system.

We attach as DOCUMENT NO. 4 the paper print-out of the information that may be obtained on the defendant on this page; and as DOCUMENT NO.5, a simple informative note on LABORATORIOS BELMAC, S.A., obtained from the Central Companies Register.

B) The agreements signed by LABORATORIOS BELMAC, S.A. and ETHYPHARM, S.A. for the manufacture of Omeprazole according to patent ES 9301319

In order to manufacture Omeprazole in Spain, ETHYPHARM, S.A. established commercial relations with the firm LABORATORIOS BELMAC, S.A.. By virtue of the agreements signed in this regard, the defendant undertook a commitment with the plaintiff to manufacture on an exclusive basis for ETHYPHARM, S.A. the Omeprazole ordered from my client and also to purchase from ETHYPHARM, S.A. the Omeprazole ordered from its own customers. The reason was very simple: my client provided LABORATORIOS BELMAC, S.A. with the necessary technological equipment to manufacture Omeprazole according to patent ES 9301319.

As proof of the foregoing and DOCUMENT NO. 6, we attach the manufacture contract of 23rd March 2000 and the purchase commitment contract of the same date formalising the grounds of the commercial relation that ETHYPHARM, S.A. and LABORATORIOS BELMAC, S.A. had maintained over the years.

Both of these documents are signed on behalf of LABORATORIOS BELMAC, S.A. by Mr. Adolfo Herrera, General manager of the company.

In the first agreement, LABORATORIOS BELMAC, S.A. undertook the commitment to *"manufacture and deliver the product manufactured at its facilities, detailed in the Appendix, following reception of the order from ETHYPHARM, S.A."*. The Appendix contains reference to

"Microgranules of Omeprazole, according to patent no. 9207249"

As may be seen in Document no. 3 attached hereto, this number corresponds to the French patent, which has priority over the Spanish.

In the purchase commitment letter, LABORATORIOS BELMAC, S.A. undertakes the following commitment:

> *"To purchase on an exclusive basis from ETHYPHARM its own needs and those of its customers, as long as ETHYPHARM guarantees such supply, in the timeframe and form established in the orders, at competitive market prices and that the product (microgranules of Omeprazole) is manufactured by BELMAC on its own premises".*

C) The machinery owned by ETHYPHARM, S.A. installed at the LABORATORIOS BELMAC, S.A. factory for the production of Omeprazole according to patent no. ES 9301319

In order to facilitate the production of Omeprazole according to ETHYPHARM, S.A.'s own technology, my client provided the necessary machinery to LABORATORIOS BELMAC, S.A. at its own Zaragoza plant. In this regard, we hereby attach:

- As DOCUMENT NO.7, the sworn statement from LABORATORIOS BELMAC, S.A. dated 6th November 1992, with the signature of its then General Manager Mr. Angel Pérez de Ayala, which acknowledged, among other facts, the following:

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" 1. That LABORATORIOS BELMAC, S.A. is negotiating with ETHYPHARM, S.A. the signing of a manufacture and collaboration contract as part of the line of contract projects and relations that both parties have been preparing an developing in recent months.

2. That parallel to these negotiations and during the course of the latter, ETHYPHARM has at its own cost carried out work and installations within part of the building owned by LABORATORIOS BELMAC, S.A. located at Polígono de Malpica Calle C, no. 4 (Zaragoza). The cost of the installations and adaptations carried out to date reaches a total figure of 27,119,843 Ptas. plus the corresponding VAT.

Similarly, ETHYPHARM has installed machinery that is identified and recognised by LABORATORIOS BELMAC, S.A. as also being entirely and totally owned by the former entity and included in this list that accompanies this document".

- As DOCUMENT NO. 8, the list of the machinery owned by ETHYPHARM, S.A. and the photograph of the room where part of this machinery was placed.

D) The explicit recognition by LABORATORIOS BELMAC, S.A. of the technology inherent in patent ES 9301319 held by ETHYPHARM, S.A and of the business effort made by the plaintiff at the defendant's plant

The assistance given by ETHYPHARM, S.A. to LABORATORIOS BELMAC, S.A. afforded the latter its commercial take-off, due to its specialisation in the manufacture and sale of Omeprazole according to ETHYPHARM, S.A.'s technology. The documents attached hereto prove the extent to which LABORATORIOS BELMAC, S.A. received the necessary means for carrying out its industrial activity from ETHYPHARM, S.A.

- As DOCUMENT NO. 9, we attach the letter of 20th March 1991 from Mr. Clemente González Azpeitia, acknowledging, among other things, the following:

  "The truth is that our personnel, with the inestimable collaboration of Mr. Bernabé, are day by day adapting better to the characteristics of the new machinery and that gradually, the quality of the Omeprazole pellets is greatly improving".

- As DOCUMENT NO. 10, the statement signed by LABORATORIOS BELMAC, S.A. on 2nd March 1998m certifying the following:

  "ETHYPHARM has entered into a manufacture agreement with LABORATORIOS BELMAC, S.A.

  ETHYPHARM owns the manufacture method, the technology and the machinery used for the process of manufacturing the batches of Omeprazole. LABORATORIOS BELMAC, S.A. is authorised to use this machinery and to use the know-how for ETHYPHARM's customers.

  LABORATORIOS BELMAC, S.A. is audited on a regular basis by ETHYPHARM to ensure that the GMP is followed according to ERHYPHARM's requirements".

- As DOCUMENT NO. 11, the sworn statement from LABORATORIOS BELMAC, S.A., dated 2nd October 1998, as follows:

  "ETHYPHARM has sent BELMAC samples of the product:

- *20 mg Capsules of omeprazole (water-based formula).*

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These samples are delivered with the sole objective that Laboratorios Belmac, S.A., may first verify the quality of the product.

For a period of 10 (ten) years following the date of this agreement, BELMAC undertakes to keep secret the results of the analysis and the existence of these samples, and to send these results only to collaborators and advisers that are also found by professional secrecy".

E) The Omeprazole manufactured by LABORATORIOS BELMAC, S.A. under the patent belonging to ETHYPHARM, S.A.

For the duration of the commercial relations between the parties, LABORATORIOS BELMAC, S.A. was manufacturing Omeprazole under patent no. ES 9301319 and using ETHYPHARM's machinery for the plaintiff's customers (Omeprazole Cinfa, from LABORATORIOS CINFA, S.A. and Omeprazole Leciva, from LABORATORIOS LECIVA, S.A.) and for its own customers (Belmazol, from the same LABORATORIOS BELMAC, S.A.;) Ulcometión, from LABORATORIOS FARMA; Omeprazole Davur, from LABORATORIOS DAVUR, S.L.; Omeprazole Acyfabrik, from LABORATORIOS ACYFABRIK, S.A. and Omeprazole FARMIGEL, from LABORATORIOS FARMIGEL, S.A.). As regards this Omeprazole manufactured in the past by LABORATORIOS BELMAC, S.A., we hereby attach the following:

- As DOCUMENT NO. 12, a complete dossier or protocol for the manufacture of the speciality Omeprazole for each of the batches manufactured by LABORATORIOS BELMAC, S.A. in March 2001 for ETHYPHARM, S.A.. This dossier contains the final balance indicating the manufacture formula.

- As DOCUMENT NO. 13, the technical records corresponding to the marketing authorisations granted by the Spanish Medicine Agency for the specialities Belmazol 20 mg. (first authorisation 1993, revised in 2001) and Omeprazole Cinfa 20 mg. (approved in May 2000). Both contain the basic formulation that corresponds in essence with ETHYPHARM S.A.'s patent.: *"Sucrose, corn starch, mannitol, sodium carboxymethylstarch, sodium laurylsulphate, povidone, hypromellosa, hypromellosa phthalate, partially hydrogenated soya oil, talc".*

- As DOCUMENT NO. 14, for example purposes, a copy of the two production agreements entered into by LABORATORIOS BELMAC, S.A. with two other laboratories for the manufacture of Omeprazole. These agreements expressly state that *" the said microgranules have been manufactured under ETHYPHARM's patent and technology".*

FOURTH.- THE UNILATERAL INTERRUPTION OF COMMERCIAL RELATIONS BY LABORATORIOS BELMAC, S.A.

A) Termination of the manufacture contract in November 2001 by LABORATORIOS BELMAC, S.A.

In November 2001, LABORATORIOS BELMAC, S.A. decided to unilaterally terminate the manufacture contract entered into by the parties, with effect as from 23rd March 2002. We attach as DOCUMENT NO. 15 the letter sent on 14th November 2001 by LABORATORIOS BELMAC, S.A. to ETHYPHARM, S.A, announcing the termination of the manufacture contract.

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B) The negotiations commenced and the commitment undertaken by LABORATORIOS BELMAC, S.A. to cease all exploitation of the patent and machinery of ETHYPHARM, S.A. after 23rd March 2002

Obviously, the decision by LABORATORIOS BELMAC, S.A. to unilaterally terminate the contract gave rise to the corresponding conflict between the parties. Please remember that the letter received by ETHYPHARM,S.A. implied, on the one hand, that my client could not meet the orders it had already received from its customers; and on the other hand, that LABORATORIOS BELMAC, S.A. intended to continue manufacturing Omeprazole according to ETHYPHARM, S.A.'s technology and machinery for its own benefit and without having to purchase the latter from the plaintiff. The negotiations started in this regard led to the following commitment:

(a) LABORATORIOS BELMAC, S.A. would meet the orders from ETHYPHARM, S.A. that had already been accepted prior to the termination.

(b) The machinery owned by ETHYPHARM, S.A and granted to LABORATORIOS BELMAC, S.A., would be used exlcusiveley to manufacture the orders for Omeprazole from ETHYPHARM, S.A.

(c) LABORATORIOS BELMAC, S.A. would cease after 23rd March 2002 from any manufacture of Omeprazole for itself and its own customers, inasmuch as the authorisation from ETHYPHARM, S.A. to exploit patent no. 9301319 was also considered to have been repealed; and

(d) As the activity of LABORATORIOS BELMAC, S.A. regarding Omeprazole would necessarily be reduced, ETHYPHARM S.A. would proceed to gradually remove the mahcinery it had granted.

Thus, from 23rd March 2002, LABORATORIOS BELMAC, S.A. could only manufacture batches of Omeprazole for ETHYPHARM S.A.'s customers. The brands corresponding to these batches were as follows:

- Omeprazole CINFA from LABORATORIOS CINFA, S.A.

- Omeprazole LECIVA from LABORATORIOS LECIVA, S.A.

We attach as proof of the foregoing:

- As DOCUMENT NO. 16, the letter dated 18th April 2002 from ETHYPHARM, S.A. to LABORATORIOS BELMAC, S.A. specifying that after the break-up in the contractual relationship, the machinery owned by my client could only be used to manufacture its own orders and that any activity carried out by LABORATORIOS BELMAC, S.A. with Omeprazole other than in strict compliance with these orders would constitute a violation of patent ES 9301319.

- As DOCUMENT NO. 17, the letter dated 31st May 2002 from ETHYPHARM, S.A. to LABORATORIOS BELMAC, S.A. expressing its concern about the possible manufacture by these laboratories of Omeprazole for its own customers, thus violating the patent in question.

- As DOCUMENT NO. 18, the letter dated 10th June 2002 from LABORATORIOS BELMAC, S.A. undertaking the commitment to meet the pending orders using the machinery owned by ETHYPHARMA, S.A. solely to manufacture same.

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C) The final removal, after several attempts to do so, of ETHYPHARM S.A.'s machinery in September 2003

Once the pending orders for Omeprazole placed by ETHYPHARM, S.A. had been completed, my client wished to remove the machinery from LABORATORIOS BELMAC, S.A. in order to prevent the defendant from continuing to use it, which would infringe the rights of the former. The following attached documentation serves as sufficient proof of the setbacks suffered by ETHYPHARM, S.A. until the machinery was returned:

- As DOCUMENT NO. 19, we attach the letter dated 11th June 2002 from ETHYPHARM, S.A. annoucning the imminent removal of the machinery in question.

- As DOCUMENT NO. 20, a selection of the correspondence exchanged between the parties in the month of September regarding the refusal by LABORATORIOS BELMAC, S.A. to allow the removal of this machinery due to supposed technical inconveniences.

- As DOCUMENT NO. 21, the notary instrument issued by the Notary of Zaragoza Mr. Juan Miguel Belloch Fernández de Palencia on 12th September 2002 attesting to the refusal by LABORATORIOS BELMAC, S.A. to allow the technicians and removal staff of ETHYPHARM, S.A. to access its factory in order to remove the latter's machinery.

- As DOCUMENT NO. 22, the letter from LABORATORIOS BELMAC, S.A. ratifying its position that the machinery may not be removed before 14th October 2002.

- As DOCUMENT NO. 23, the agreement signed by the parties on 9th September 2003 reflecting the disassembly and removal of ETHYPHARM, S.A.'s machinery between 19th August 2003 and the aforementioned date. In this agreement, the parties obviously acknowledged that *"there are no claims regarding the removal of the machinery and the repair of the facilities"*.

In other words, LABORATORIOS BELMAC, S.A. was able to continue using the said machinery for its own interests between 23rd March 2002 and 19th August 2003.

FIFTH.- THE UNCONSENTED EXPLOITATION BY LABORATORIOS BELMAC, S.A. OF ETHYPHARM S.A.'s PATENT AND TECHNOLOGY BETWEEN 23RD MARCH 2002 AND 19TH DECEMBER 2002

(A) The appearance on the market of Omeprazole products manufactured by LABORATORIOS BELMAC, S.A. after 23rd March 2002

My client very soon realised that the reason why LABORATORIOS BELMAC, S.A. had terminated the contract was none other than in order to continue manufacturing Omeprazole using the patent and technology owned by ETHYPHARM, S.A. without the need to purchase them from the plaintiff. In this regard, we attach as DOCUMENT NO. 24, a photocopy of the selection of Omeprazole pharmaceutical products manufactured by LABORATORIOS BELMAC, S.A. that this party found in the market in October 2002. From the best-before dates on these batches of Omeprazole, it is obvious that they had been manufactured after 23rd March 2002.

The table referring to these products is as follows:

Trademark	Laboratory	Batch	Best Before	Manufactured
Belmazol	BELMAC, S.A.	S 12	07 2005	July 2002
Ulcometion	ANTIBIÓTICOS FARMA, S.A.	S 07	07 2005	July 2002
Omeprazole	LABORATORIOS DAVUR,	S 30	07 2004	July 2002

Davur	S.L.			
Omeprazole Acyfabrik	LABORATORIOS ACYFABRIK, S.A.	S 05	07 2004	July 2002
Omeprazole Farmygel	LABORATORIOS FARMYGEL, S.A.	S 14	09 2004	September 2002

The following explanations are expressly provided:

(a) That the letter "S" contained on the batch refers to the year of manufacture 2002.
(b) That the latest best-before date normally allowed for this type of pharmaceutical specialities, in the case of branded products (Belmazol and Ulcometion), is three years: therefore, if these batches carry "07 2005" as the best-before date, they were manufactured in July 2002.
(c) That the latest best-before date normally allowed for this type of pharmaceutical specialities, in the case of generic medicines (Omeprazole Davur, Omeprazole Acyfabrik and Omeprazole Farmygel) is two years: therefore the batches whose best-before date is 2004 were manufactured in 2002, in the month indicated on the side.

The conclusion to be reached here is quite clear: LABORATORIOS BELMAC, S.A. was taking advantage of the resources and technology provided by ETHYPHARM, S.A. and manufacturing its own Omeprazole for third-party companies, using the latter's own machinery and patent to do so.

B)The fact verification proceedings carried out in Zaragoza at the LABORATORIOS BELMAC, S.A. plant, on 19th December 2002

In order to verify if LABORATORIOS BELMAC, S.A. was still making use of the formulation claimed in the invention patent no. ES 9301319 and if it was still continuing to manufacture Omeprazole for third parties using ETHYPHARM, S.A's machinery, the latter requested that preliminary proceedings be practised at the defendant's plant in Zaragoza. The following aspects should be highlighted from the substantiation and resolution of the said proceedings:

(a) The application for fact verification proceedings was admitted by the Court of First Instance no. 72 of Madrid in Instrument of 5th November 2002. The Court's decision contains the authorisation for Mr. Domingo Bernabé from ETHYPHARM, S.A. to act as *practicum* in these proceedings and the appointment as expert of Mr. Rafael Sánchez Guillermo, in possession of a Degree in Pharmacy. The Court agreed that the proceedings be carried out by means of letters rogatory.

(b) The Court of First Instance no. 14 in Zaragoza carried out the proceedings at the factory and offices of LABORATORIOS BELMAC, S.A., at Malpica Industrial Estate on 19th December 2002 after 11.00 o' clock a.m.. Mr. Rafael Sánchez Guillermo, as the independent expert, Mr. Domingo Bernabé, as practicum for ETHYPHARM, S.A. and the undersigning solicitor participated in the proceedings. The Legal Secretary issued the corresponding handwritten instrument, which was later transcribed to computerised format. After the proceedings had been carried out, the reports were sent back to the Court of First Instance in Madrid.

(c) ETHYPHARM, S.A. immediately requested that the Court of First Instance in Madrid deliver the judicial evidence needed to prepare the main suit. LABORATORIOS BELMAC, S.A. however, came before the Court of First Instance no. 72 of Madrid to oppose delivery of this evidence, thus causing the corresponding incident. The Hearing was held on 3rd February 2003 and the incident was settled by Court Instrument of 19th January 2005, notified on 10th February of this year.

The Court of First Instance no. 72 of Madrid did not accept the opposition and ordered that the evidence be delivered to my client.

These points are proven by the following attached documents:

- As DOCUMENT NO. 25, a copy of the document applying for fact verification proceedings presented in October 2002.

- As DOCUMENT NO. 26, a copy of the Instrument from the Court of First Instance no. 72 of Madrid, dated 5th November 2002 and of the decision of 18th of the same month, accepting the application for proceedings and agreeing to send the respective letter rogatory.

- As DOCUMENT NO. 27, a copy of the Instrument dated 19th January 2003 from the Court of First Instance no. 72 of Madrid, refusing the opposition presented by LABORATORIOS BELMAC, S.A. and ordering the evidence of the proceedings carried out in Zaragoza to be delivered to ETHYPHARM, S.A.

- As DOCUMENT NO. 28, the original evidence issued by the Court of First Instance no. 72 of Madrid regarding the proceedings carried out in Zaragoza. The evidence was issued and delivered to this party on 15th February 2005, as may be seen on the last page with the signature of the Legal Secretary.

C) The technical verification of the infringement: expert's report provided on the documentation seized in Zaragoza

Once the evidence of the proceedings carried out in Zaragoza was received, ETHYPHARM, S.A. entrusted analysis of the seized documentation to the expert Mr. Rafael Sánchez, who had participated in the proceedings. The analysis of the documentation may be summarised in the following items:

(a) The expert commences his analysis by *paginating and numbering* the specific content of the documentation contained in the judicial evidence. He does so, logically, in APPENDIX I of his report, which constitutes the full photocopy of the evidence. The pagination is as follows:

- Folios 1 to 21: Handwritten instrument detailing the proceedings carried out in Zaragoza and a typed transcription of same;

- Folios 22 to 28: photocopies of the most relevant pages in the batches of Omeprazole micro pellets that were being manufactured at the time of the inspection;

- Folios 29 to 33: photocopy of the most relevant pages of the batches of Omeprazole micro pellets corresponding to the products manufactured by LABORATORIOS BELMAC, S.A., which had been acquired by ETHYPHARM, S.A. in October 2002: Omeprazole Cinfa, Omeprazole Leciva, Belmazol, Ulcometión, Omeprazole Davur, Omeprazole Acyfabrik and Omeprazole Farmygel;

- Folios 34 to 211: the complete manufacture dossiers on these same batches of Omeprazole;

- Folios 242 bis to 246: official communications from the Spanish Medicine Agency;

- Folios 247 to 248: photocopies of prospects and cardboard packaging of the Omeprazole found in the stores.

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At the Court's request, the expert shall proceed to give this same pagination to the court evidence provided.

(b) The report also contains, as a general consideration, the description and explanation of the content and scope of invention patent no. ES 9301319. The expert confirms that this is a patent whose claims 1 to 6 refer to a pharmaceutical formulation or product. Mr. Rafael Sánchez informs that claim no. 1, the main claim, contains the essential characteristics of the patented formulation and that claims 2 to 6, which depend on the 1st, contain certain additional characteristics. His words in this regard are as follows:

" – The essential characteristics of the formulation patented in Ethypharm's Spanish patent no. 9301319, contained in claim 1, are as follows:

- *Stable formulation of omeprazole in form of granules*
- *Containing a neutral nucleus based on sugar and starch*
- *Plus an active layer based on a dilution of omeprazole in mannitol, in perceptibly equal quantities.*

- *The characteristics that are additional to the above essential characteristics are protected in claims 2 to 6, which depend on claim 1. The formulation may also contain:*

  - *10% weight of carboxymethylstarch in the active layer (claim 2)*
  - *5% of a tensioactive substance such as sodium laurylsulphate in the active layer (claim 3)*
  - *Mannitol on the surface of the active layer in the form of a complementary protective layer (claim 4)*
  - *A binding agent such as hydroxypropylmethylcellulose (claim 5)*
  - *A gastro-resistant coating such as Hydroxypropylmethylcellulose Phthalate and talc (claim 6)"*

(c) The initial object of the proceedings was to verify if LABORATORIOS BELMAC, S.A. was still, in December 2002, using the machinery provided by ETHYPHARM, S.A. to manufacture Omeprazole for orders other than those pending for the plaintiff. The instrument that is attached to the evidence attests that the Judicial Committee entered the Room where the microgranules were prepared and the micro-pellets were manufactured and the machinery provided by ETHYPHARM, S.A. was functioning. At the request of this party, part of the dossiers corresponding to the micro pellets being manufactured were photocopied: batches Z 104, Z 112 and Z 093. The Manager of the Manufacturing Department at LABORATORIOS BELMAC, S.A. , Mr. Francisco Poderos, declared that he was not aware of who the "addressee" of the aforementioned batches was. After analysing the documentation, the expert has concluded that the batches being manufactured in December 2002 meet ETHYPHARM, S.A.'s patent. Mr. Rafael Sánchez examines this on a claim by claim basis:

" a) The formulation of the batches of OMEPRAZOL is included in claim 1 of ETHYPHARM, S.A.'s patent, for the following reasons:

- *The product produced by LABORATORIOS BELMAC, S.A. is a formulation in the form of stable microgranules;*
- *The granules contains a neutral nucleus of sugar and starch (as may be seen in the final balance on page 24 of APPENDIX I);*
- *The granules contain, as well as the neutral nucleus, an active layer of a mixture of OMEPRAZOL and mannitol (same page); in this active layer, the quantities of OMEPRAZOL and mannitol are perceptibly equal (5 kilos of OMEPRAZOL, 5 kilos of mannitol: see, for example, page 23 of APPENDIX I);*

b) *The formulation of the batches of OMEPRAZOL is also covered in claim 2 of ETHYPHARM, S.A.'s patent because it has an active layer containing carboxymethyl starch (Explotab). This appears on pages 23, 24, 26, 28, 29, 30, 31, 32 and 33.*

c) *The formulation of the batches of OMEPRAZOL is also covered in claim 3 of ETHYPHARM, S.A.'s patent because the active layer of OMEPRAZOL contains sodium laurylsulphate. This appears on pages 23, 24, 26, 28, 29, 30, 31, 32 and 33.*

d) *The formulation of the batches of OMEPRAZOL is also covered in claim 4 of ETHYPHARM, S.A.'s patent because the active layer of OMEPRAZOL contains a complementary protective coating composed of mannitol. This may be deduced from the final balances on pages 24, 26 and 28, where we can see a final quantity of mannitol that is higher than the ratio used in the formulation for the microgranules.*

e) *The formulation of the batches of OMEPRAZOL is also covered in claim 5 of ETHYPHARM, S.A.'s patent because in order to bind the active layer to the neutral nucleus, a binding agent in solution form is used (this is proven in the final balance on folio 24); this binding agent is of the Hydroxypropylmethylcellulose type (Pharmacoat or hypromellosa).*

f) *The formulation of the batches of OMEPRAZOL is also covered in claim 4 of ETHYPHARM, S.A.'s patent because the formulation presents an outer gastro-protective coating composed of hydroxypropylmethylcellulose phthalate (HP 50) and talc. This appears on pages 24, 26 and 28".*

The files at LABORATORIOS BELMAC, S.A. are indicated as proof to find out the final destination of these batches being manufactured.

(d) The second objective of the proceedings was to determine the date of manufacture and formulation of the batches of Omeprazole from LABORATORIOS BELMAC, S.A. that ETHYPHARM had acquired in the market. The intention was to determine if they had been manufactured after 23rd March 2002, date on which the defendant had to cease using the technology belonging to this party. At the plaintiff's request, the manufacture dossiers of the aforementioned batches of Omeprazole Cinfa, Omeprazole Leciva, Belmazol, Ulcometión, Omeprazole Davur, Omeprazole Acyfabrik and Omeprazole Farmygel were photocopied at LABORATORIOS BELMAC, S.A.'s plant. Following analysis of these batches by the expert, it is confirmed that they were all manufactured by LABORATORIOS BELMAC, S.A. between 16th June 2002 and 2nd September 2002 and that the formulation referring to these batches is substantially equal to that of ETHYPHARM, S.A.'s patent ES 9301319. To be specific, the expert addresses this issue as follows:

"- The product produced by LABORATORIOS BELMAC, S.A. is a formulation in the form of stable granules;

- *In the informative slip for these batches included on pages 73, 106, 153, 182 and 208, the full formula, which is substantially identical to that of ETHYPHARM, S.A.'s patent 9301319;*

- *The granules contain, as well as a neutral nucleus, an active layer of a mixture of OMEPRAZOL and mannitol (as may be seen on pages 29, 30, 31 and 32);*

- *The quantities of OMEPRAZOL and mannitol are perceptibly equal in this active layer (5 kilos in each one: pages 29, 30, 31 and 32);*

Moreover, the documentation indicates that claims 2 and 3 of the patent have also been infringed:

- *The formulation of the batches of OMEPRAZOL is also covered by claim 2 of ETHYPHARM, S.A.'s patent, because it includes an active layer containing carboxymethylstarch (Explotab). This appears on pages 29, 30, 31, 32 and 33 of APPENDIX I.*

- *The formulation of the batches of OMEPRAZOL is also covered by claim 3 of ETHYPHARM, S.A.'s patent, because the active layer of OMEPRAZOL contains sodium laurylsulphate. This appears on pages 29, 30, 31, 32 and 33 of APPENDIX I.*

If we had the final balance of these manufacture batches (pages 33 of 33 of the Manufacture Protocol), we could verify the presence of the components described in claims 4 to 6".

As for claims 4 and 6, the expert cannot make a statement because the full dossiers for batches Z 022, Z 030, Z 033 and Z 051 are missing.

(e) During the course of the proceedings, the judicial committee also entered the Encapsulation and Conditioning Rooms and the store at LABORATORIOS BELMAC, S.A.. The instrument and the seized documentation contain references to the batches of Omeprazole Davur that had been encapsulated and conditioned recently and the products Ulcometión, Omeprazole Davur, Omeprazole Acyfabrik, Belmazol 20 mg. and Omeprazole Farmygel that were in the store and of which the corresponding samples were seized. The expert was able to ascertain from the best-before date and by the formula described in these informative slips, that the Omeprazole had been manufactured after March 2002 and according to the formulation contained in patent no. ES 9301319.

(f) Finally, during the proceedings, LABORATORIOS BELMAC, S.A. was asked to provide a manufacture dossier for the Omeprazole that it had manufactured in the past under ETHYPHARM, S.A.'s patent and using its technology. There is a photocopy in the evidence of a batch manufactured in March 1998, the final balance of which, as the expert confirms, coincides in essence with ETHYPHARM, S.A.'s patent ES 9301319 and also with the manufacture dossier that was given to the expert and which constitutes APPENDIX III of the latter's report. It is interesting to highlight that Mr. Rafael Sánchez analyses in his report if the final balance that appears in these dossiers corresponds to the formulation in ETHYPHARM, S.A.'s patent and indicates in this regard:

"...the components used in the preparation are as follows:

(a) On the one hand, the essential components in ETHYPHARM's patent and described in claims 1 to 6: NHB (OMEPRAZOL); NEUTRALS (Sucrose and Starch); MANNITOL; EXPLOTAB (Sodium Carboxymethylstarch); SODIUM LAURYLSULPHATE;

FARMACOAT (Hydroxypropylmethylcellulose); HP 50 (Hydroxypropylmethylcellulose Phthalate).

b) On the other hand, this manufacture dossier also describes the following components: PVP K30 (Polyvinylpyrrolidone); MYVACET (Plastifying agent based on hydrogenated soya oil); ISOPROPYL ALCOHOL; ETHYL ALCOHOL and METHYLENE CHLORIDE (Dichloromethane). Of these components, the ISOPROPYL ALCOHOL, the ETHYL ALCOHOL and METHYLENE CHLORIDE disappear by evaporation during the process of manufacturing the formulation and are not included in its final composition. As for PVP, it is one of the binding components equivalent to FARMACOAT 606 (Hydroxypropylmethylcellulose). MYVACET is a plastifying agent normally used in the pharmaceutical industry".

(g) Lastly, we should add that the Court asked LABORATORIOS BELMAC, S.A. to show some additional documentation: the orders for Omeprazole received by this company after 24th March 2002; the sales invoices for various Omeprazole specialities after this same date; the delivery notes for Omeprazole manufactured for the firms ANTIBIÓTICOS FARMA, LABORATORIOS DAVUR, LABORATORIOS ACYFABRIK and LABORATORIOS FARMYGEL after 24th March 2002 and the manufacture and sale contracts and/or the licenses for the pharmaceutical authorisation,

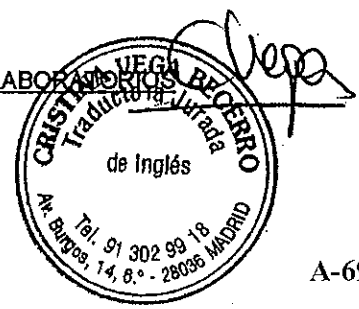
entered into after the said date by the defendant. The instrument contains a statement from the Technical Director of this company saying that this documentation was to be found at LABORATORIOS BELMAC, S.A.'s corporate office in Madrid.

We attach as DOCUMENT NO. 29, the original decision issued by Mr. Rafael Sánchez Guillermo and the Appendices that belong to same. Please note the statement contained in this report:

" I hereby state that both as regards the prior inspections and verifications and as regards the decision issued, I have acted, and will act, with the greatest possible objectivity, taking into consideration both what may favour and what may harm either of the two parties and I am aware of the penal sanctions in which I could incur if I were to fail to perform by duties as expert".

SIXTH.- THE PERSISTENCE OF LABORATORIOS BELMAC, S.A. IN THE INFRINGEMENT AFTER THE FACT VERIFICATION PROCEEDINGS WERE CARRIED OUT IN DECEMBER 2002

(A) The capsules of Omeprazole manufactured by LABORATORIOS BELMAC, S.A. after 19th December 2002



In the period elapsed between the carrying out of the proceedings in December 2002 and the settlement of the incident by the Court of First Instance no. 72 of Madrid in February 2005, LABORATORIOS BELMAC, S.A. continued to manufacture Omeprazole according to the formulation in patent ES 9301319. This manufacture was presumably carried out using the machinery owned by ETHYPHARM, S.A. until 9th September 2003, on which date the machinery was removed. We shall refer in particular to the following products:

- A batch of Belmazol 20mg. Capsules of Omeprazole (S1), whose best-before date is January 2005, meaning that it would have been manufactured in January 2003.

- A batch of Davur 20mg. (V 008), whose best-before date is January 2006, meaning that it would have been manufactured in January 2004.

- A batch of Belmazol 20mg. (V 003), whose best-before date is January 2006, meaning that it would have been manufactured in January 2004.

- A batch of Omeprazole Farmygel (V 034), whose best-before date is September 2006.

We hereby attach, as DOCUMENT NO. 30, the photocopies of the packaging and informative slips for these products. The originals were sent, as shall be explained now, for technical analysis. They contain a reference to LABORATORIOS BELMAC, S.A. as manufacturer. For the purposes of evidence, we indicate not only the manufacture dossiers contained in LABORATORIOS BELMAC, S.A.'s files, but also the defendant's own library of samples of the capsules corresponding to these batches.

(B) The inexistence of any change in the formulation: the absence of the new health registrations obtained by LABORATORIOS BELMAC, S.A. for marketing Omeprazole

The fact that LABORATORIOS BELMAC, S.A. maintained the same Omeprazole manufacturing formula as provided by ETHYPHARM, S.A. at the time is clearly demonstrated by the lack of new health registrations obtained for this purpose by the defendant. In this regard, we hereby attach the following:

- As DOCUMENT NO. 31, the paper print-out of the pages of the website www.belmac.com regarding the Belmazol manufactured by the defendant. They contains the two technical files authorised by the Spanish Medicine Agency to this company. These files are as follows: Belmazol 20 mg. (First authorisation in January 1993, revised in February 2001) and Belmazol 10 mg. (June/ September 2003). You will remember that the first technical file was the one obtained during the period of relations between ETHYPHARM, S.A. and LABORATORIOS BELMAC, S.A.. Well, the formulation of the latter technical file obtained by LABORATORIOS BELMAC, S.A. for Omeprazole is identical to the former. The only perceptible change is in the coating for the gelatine capsule (the addition of iron oxide), which does not affect the actual formulation of the product.

- As DOCUMENT NO. 32, we provide the full list of pharmaceutical specialities granted by the Spanish Medicine Agency and which may be consulted on the webpage of this public Body. It does not include any pharmaceutical speciality granted to LABORATORIOS BELMAC, S.A. after June 2003.

(C) The irrelevance of ulterior patents obtained by LABORATORIOS BELMAC, S.A. for Omeprazole

This party has been informed that LABORATORIOS BELMAC, S.A. has obtained registration for an invention patent for an *"improved process for obtaining stable and gastro-resistant pellets of Omeprazole, pellets thus obtained and applications"*. This patent was applied for on 6th April 2001 and was recently granted by the Spanish

Patents and Trademarks Office. Its relevance in the issue being debated in this proceeding is null, apart from the legal questions that will be exposed later on, if one realises the analysis carried out by the expert Mr. Rafael Sánchez in his report. According to the expert, the patent held by LABORATORIOS BELMAC, S.A. *would be included in ETHYPHARM's patent no. 9301319 for the following reasons:*

"a) The patent refers to procedures for obtaining stable pellets of Omeprazole whose formulation is substantially identical to the one protected in claims 1 to 6 of ETHYPHARM's patent. In particular, the formulation includes the following essential components:

- *Neutral agents (Sucrose and starch)*
- *Omeprazole*
- *Mannitol (concentration substantially identical to that of Omeprazole)*
- *Carboxymethylstarch*
- *Sodium Laurylsulphate*

b) The only components present in the formulation of patent ES 2192929 in comparison to ETHYPHARM's patent would be the following:

- *Polyvinylpyrrolidone (which is a binding agent equivalent to the Pharmacoat or hydroxypropylmethylcellulose claimed in ETHYPHARM's patent)*
- *Isopropyl Alcohol (which disappears in the manufacture process and therefore does not make up the final composition of the formulation)*

c) These components were already being used prior to the date of application for BELMAC's patent, as is shown in the dossier provided as APPENDIX III".

We hereby attach as DOCUMENT NO. 33, the text of patent number 2192929 held by LABORATORIOS BELMAC, S.A., which may be obtained from the database of the Spanish Patents and Trademarks Office.

D) The additional technical verification provided for the current Omeprazole manufactured by LABORATORIOS BELMAC, S.A.

Although the evidence and indications point to the fact that LABORATORIOS BELMAC, S.A. continued to manufacture Omeprazole according to the formulation claimed in patent number ES 9301319 and using the technology provided by ETHYPHARM, S.A., my client wished to subject the most recent capsules of Omeprazole on the market to a technical analysis.

We provide in this regard and as DOCUMENTS NOS. 34, 35 and 26, the reports issued by Professor Robert Rosset in April of this year, analysing respectively one tablet of Omeprazole from the batches purchased by ETHYPHARM, S.A. and mentioned previously in this writ. The final result or conclusion to all the tests, after analysing the Omeprazole microgranules using the infra-red spectrometry technique is unequivocal: the percentage of Omeprazole and mannitol used substantially coincides with the quantities claimed in patent no. ES 9301319.

Medicine	Batch	Best-before date	% Omeprazole	% Mannitol
BELMAZOL 20 mg	S1	01.2005	52.1	47.9
DAVUR 20 mg	V008	01.2006	52	48

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BELMAZOL 20 mg	V003	12.2006	44.4	55.6

SEVENTH.- THE LOSSES AND DAMAGES DERIVED FROM VIOLATION OF ETHYPHARM, S.A.'s PATENT AND FROM THE UNLOYAL BEHAVIOUR OF LABORATORIOS BELMAC, S.A.

(A) The mark-up that the sale of the Omeprazole manufactured by LABORATORIOS BELMAC, S.A. represented for ETHYPHARM

The relations between ETHYPHARM, S.A. and LABORATORIOS BELMAC, S.A. for Omeprazole were based on the setting of a price for the sale of the product manufactured by the defendant. This price varied depending on whether the product was Omeprazole corresponding to an order from ETHYPHARM, S.A., Omeprazole manufactured for internal consumption by LABORATORIOS BELMAC, S.A. (its own products or orders from its customers) and Omeprazole destined for export. The mark-up obviously varied over the years This party has calculated the corresponding average as 250 Euros per kilo of Omeprazole converted to microgranules. We can now confirm the presentation of an accounting report, which was not available at the time the suit was filed, confirming this data.

B) Quantification of the damages from the manufacture and sale of Omeprazole from 23rd March 2002 onwards

The compensation for losses and damages should be calculated on the basis of the units sold and the kilos of Omeprazole manufactured by LABORATORIOS BELMAC, S.A. after 23rd March 2002 and until the date on which the sentence to this suit is issued. For the purposes of evidence, this party hereby states the following:

- First of all, we provide, as DOCUMENTS NOS. 37 and 28, the certificates issued by the specialist company IMS HEALTH, S.A. on the units sold and the total turnover of the Omeprazole specialities in the years 2002, 2003 and 2004.

- We indicate LABORATORIOS BELMAC, S.A.'s files because of the obligation that they be revealed. In the ADDITIONAL PLEADING, LABORATORIOS BELMAC, S.A. is specifically requested to provide the Court with a certificate, approved by its auditor, containing the following information: (i) Omeprazole pharmaceutical specialities manufactured by LABORATORIOS BELMAC, S.A. for its own products or for third parties and destined for export after 23rd March 2002 (ii) kilos of Omeprazole manufactured since 23rd March 2002 for the aforementioned pharmaceutical specialities.

- We propose as evidence, also in the ADDITIONAL PLEADING, that the Court appoint an expert accountant so that by analysing the invoices, official books, accounting documents and any other necessary document owned by the company ETHYPHARM, S.A. or by the defendant LABORATORIOS BELMAC, S.A., it may be possible to certify: (i) the average price that LABORATORIOS BELMAC, S.A. paid to ETHYPHARM, S.A. for the manufacture and sale of Omeprazole pharmaceutical specialities (ii) the price that LABORATORIOS BELMAC, S.A. should have paid to ETHYPHARM, S.A. for the manufacture and sale by LABORATORIOS BELMAC, S.A. of Omeprazole specialities after 23rd March 2002.

GROUNDS OF LAW

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